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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/553,946

10/21/2005

Atsushi Tendo

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5815

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EXAMINER

GALLIS, DAVID E

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

03/06/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/553,946 | <b>Applicant(s)</b><br>TENDO ET AL. |  |
|                              | <b>Examiner</b><br>DAVID E. GALLIS   | <b>Art Unit</b><br>1625             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3,4 and 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

- 1.
2. The final rejection is withdrawn.
3. Claims 3, 4 and 7 are pending. Claims 1, 2, 5 and 6 have been canceled.

Applicant's claim to foreign priority from application Japan 2003-121103 filed April 25, 2003 is acknowledged. Applicant's amendments and arguments filed after final on November 4, 2008 have been entered and carefully considered.

***Prior Rejections***

4. With regard to the prior rejection of claims 1, 2, 5 and 6 under 35 U.S.C. 102(a) and (e), Applicants have canceled claims 1, 2, 5 and 6 outright. Therefore the rejection of claims 1, 2, 5 and 6 as anticipated by Nomura et al. is hereby withdrawn.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nomura et al., US 6,387,908 B1, May 14, 2002 ('908), and their application 09/508026 filed May 5, 2000, and in further view of Stahl et al. (Handbook of Pharmaceutical Salts, Properties, Selection, and Use., Verlag Helvetica Chimica Acta, Zurich, 2002).
7. Claim 7 is drawn organic amine salts of (2S,3S)-3-[[[(1S)-1-isobutoxymethyl-3-methylbutyl]carbamoyl]oxirane-2-carboxylate, including piperazine, arginine, lysine, and benzathine. Nomura et al. teach the same epoxysuccinamide derivative (Table 1,

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Column 9, Compound No. 87) and further teach that the base of this derivative can form organic amine salts reciting “*The epoxysuccinamide derivative of the invention can be employed in the form of a physiologically acceptable salt. For example, in the case that  $R^1$  is a hydrogen atom and X is  $-O-$ , it forms a salt with an alkali metal (e.g., sodium or potassium), an alkaline earth metal (e.g., calcium), or an organic amine ....”*. However, Nomura et al does not specifically teach the instantly claimed organic amine counter ions. Stahl et al. remedies the deficiency of Nomura et al. by teaching, as general reference in the art, piperazine, arginine, lysine, and benzathine organic salts, and thereby establishing these organic amines as counter ions that are well known in the art and obvious to one of ordinary skill in the art (see piperazine: pages 142, 215, 267, 321, 343, 345; arginine: pages 142, 215, 267, 311, 342-345; lysine: pages 215, 262, 267, 319, 344, 345; benzathine: pages 164, 168, 267, 312). While the use of these salts are novel to the process claimed, the salts themselves are obvious to one of ordinary skill in the art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Thur 8:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/

David E. Gallis  
Patent Examiner

/ Bernard Dentz/

Primary Examiner, Art Unit 1625